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CALIFORNIA
HEALTHCARE
INSTITUTE

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Elias A. Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

On behalf of the California Healthcare Institute (CHI), whose more than 220 members include our state's premier life science companies and academic research institutions, I would like to express concern regarding the recent action to impose the march-in provision of the Bayh-Dole Act (Bayh-Dole) against Abbott Laboratories.

Healthcare access and affordability is a serious national issue, and was the focus of the recently enacted Medicare Prescription Drug and Modernization Act of 2003 (MMA). This landmark legislation will improve prescription drug coverage for our nation's seniors and most needy. Bayh-Dole, however, is not the proper vehicle for addressing concerns about drug access and costs.

Bayh-Dole was intended to stimulate the transfer of medical technology between academic institutions and commercial companies. In passing this law, Congress recognized that federal funding of basic science was, by itself, insufficient to bring new medicines to the bedside. The complex and expensive process of transforming discoveries into products required a legal framework in which the intellectual property derived from federally-funded research could be licensed by a university to a company in exchange for royalties or other appropriate considerations. To ensure that important innovations would not languish, march-in provisions were built into the law to allow government to broaden the scope of patents in order to move inventions into the market place if a commercial company lacked the resources necessary to do so. Neither Bayh-Dole nor its march-in provision pertains to the issue of affordability in the marketplace. Certainly Bayh-Dole was not intended to act as a price control mechanism.

Allowing march-in rights based on price would go against the very aim of Bayh-Dole. Indeed, the product in question, Norvir, is already available on the market and has been used effectively by patients. The government cannot encourage industry to bring products to market by extending patents only to take them away once the product is commercialized. The result would be a return to the status quo prior to enactment of Bayh-Dole when taxpayer dollars were invested in research that had minimal chance of reaching the market. By weakening intellectual property rights, the exercise of march-in rights in this case would have devastating effects on the future of medical innovation in the United States

I strongly urge NIH to consider not only the original intent of the Bayh-Dole march-in provisions but the original aim of the Bayh-Dole Act itself – to stimulate the commercialization of discovery, not stifle it – and reject exercise of march-in rights in this case.

Sincerely,

David Gollaher, Ph.D.
President & CEO

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